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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,498	01/10/2001	Preeti Lal	PF-0385-1 DIV	1324
27904	7590	01/16/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/758,498

Applicant(s)

LAL ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

1. Claims 1,5 are under consideration.

## RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (US Patent 5,312,628). Applicants arguments have been considered and deemed not persuasive.

Cohen et al. teach an autoantigen between 40 and 45 kD which reacts with autoantibodies from diabetic humans. According to the specification, page 24, penultimate paragraph, the claimed peptide is an autoantigen involved in diabetes. The size of the molecule is similar to that recited in claim 1 (eg. approximately 39,500). The art recognizes that SDS-polyacrylamide gels would render a molecular weight that is not exact but is an approximation due to experimental variation inherent in the technique (for example, column 5, paragraph 1 indicates that the molecule is referred to as 42 kDa but is between about 40 and 45 kDa). Cohen et al. teach that said antigen preparation would be administered to humans (see column 8, second paragraph). Said antigen would be administered in a suitable excipient. The amino acid sequence is an inherent property of said molecule.

Regarding applicants comments, according to the specification, imogen 38 leads to the generation of imogen 38 reactive antibodies which are only found in patients with diseased pancreatic tissue (see page 2). According to the specification the claimed

protein is a human homolog of imogen 38 (see page 24, penultimate paragraph) and would therefore be expected to have similar properties. The Lieberman et al. reference does not disclose that their antigen leads to the generation of autoantibodies which are only found in patients with diseased pancreatic tissue. Cohen et al. teach an autoantigen between 40 and 45 kD which reacts with autoantibodies from diabetic humans. Regarding the antigen disclosed in Honeyman et al., imogen 38 reactive antibodies are found in patients with diseased pancreatic tissue, whilst the antigen disclosed by Honeyman et al. is not found in all IDDM patients. Cohen et al. teach an autoantigen between 40 and 45 kD which reacts with autoantibodies from diabetic humans which is found in all tested diabetic serum (see Example 5). Therefore, only the antigen taught by Cohen et al. has properties that would be expected to be found by the human homolog of imogen 38.

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or

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relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800-1644

Ron Schwadron, Ph.D.

Primary Examiner

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